

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

TRUSTEES OF THE UNIVERSITY OF	)	
PENNSYLVANIA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:15-cv-06133-WB
	)	
ELI LILLY AND COMPANY,	)	
	)	
IMCLONE LLC and	)	
	)	
BRISTOL MYERS SQUIBB COMPANY,	)	
	)	
Defendants.	)	
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**PLAINTIFF’S OPPOSITION TO DEFENDANTS’ MOTION TO STAY PENDING  
*INTER PARTES* REVIEW**

Plaintiff Trustees of the University of Pennsylvania (“Penn”) respectfully submits this Brief in Opposition to the Motion to Stay Pending *Inter Partes* Review of U.S. Patent No. 7,625,558 (“the ’558 patent” or “Patent-in-Suit”) (D.I. 23) filed by Defendants Eli Lilly and Company (“Lilly”), ImClone LLC (“ImClone”), and Bristol Myers Squibb Company (“BMS”) (collectively, “Defendants”).

**I. INTRODUCTION**

Defendants’ motion to stay this case is, at the very least, premature. Defendants filed this motion one day after Lilly filed its petition for *inter partes* review (“IPR”) with the U.S. Patent and Trademark Office, Patent Trials and Appeals Board (the “PTAB”). At this stage, it is pure speculation whether the PTAB will even grant Lilly’s petition to review the ’558 patent. Until, and unless, the Patent Office grants the petition—which can come as late as July 15, 2016—there

is no legitimate reason to even consider staying this case. Discovery is ongoing, and even if the PTAB grants Lilly's IPR petition, this case could very well be decided on the merits before the conclusion of the IPR process.

Moreover, a stay is unlikely to simplify the issues in this litigation. Although Defendants' motion presumes complete success in an IPR, the reality of their prior art position suggests otherwise. As an initial matter, Lilly's petition does not even challenge the patentability of nine of the asserted claims in this case.<sup>1</sup> For the claims that are addressed, Lilly's petition relies solely on obviousness challenges under 35 U.S.C. § 103 based on attenuated combinations of three (and in one case four) references. Two of these references were extensively considered by the PTO during prosecution, and the other two are immaterial to the validity of the claims at issue. In short, Defendants' prior art attacks are weak and unlikely to prevail at the PTAB.

Perhaps this is why so much of the argument in Defendants' motion, and in the IPR petition itself, is focused not on the '558 patent, but instead on other Penn patent applications, including Penn's European application, which is subject to different patentability standards and prior art rules. Even assuming Penn's other patent prosecution activities are relevant here, which they are not, it is worth noting that in 2007 Defendants ImClone and Lilly initiated an attack on a counterpart to the '558 in the European Patent Office by filing an Opposition to Penn's European application EP1058562. Yet prior to being served with Penn's Complaint in late 2015, none of the Defendants ever sought to attack the validity of the '558 patent itself, even though Defendants derive the vast majority of their Erbitux sales revenue from sales in the United States. That Defendants never challenged the '558 patent at the PTAB until now speaks volumes about the tactical nature of Defendants' IPR petition and stay motion.

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<sup>1</sup> Defendants instead have moved to dismiss claims 32-40 from this litigation. As explained in Penn's forthcoming Opposition to Defendants Motion to Dismiss, Defendants' motion is without merit, as the Court can and should correct Claims 32-40 by deleting the references to other multiple dependent claims during claim construction.

Penn respectfully requests that the Court deny Defendants' Motion to Stay in full.

Alternatively, Penn requests that the Court Deny Defendants' Motion as premature. If the PTAB grants Lilly's IPR petition, the parties and the Court can address at that time whether a stay makes sense. In the meantime, a stay of this action will inevitably impede "the just, speedy, and inexpensive determination of" this case as guaranteed under Fed. R. Civ. P. 1.

## **II. BACKGROUND**

### **A. Penn's '558 Patent**

The '558 patent is directed to methods of treating a patient afflicted with a certain type of cancer by first administering a specific antibody and then treating the patient with anti-cancer radiation therapy. More specifically, the '558 patent is directed to treating an erbB protein-mediated tumor by first administering to the patient an antibody with erbB inhibitor properties and then exposing the patient to anti-cancer radiation.

The anti-erbB antibodies disclosed and claimed in the '558 patent bind to erbB proteins on the surface of the cancer cell and inhibit the formation of erbB protein dimers. The cancer cells rely on erbB protein dimers for cell division, and when the formation of such dimers is inhibited, the cancer cells cannot replicate. Thus, the anti-erbB antibodies employed in the '558 claims function as a cytostatic agent, one that stops cells from dividing. After treatment with the specific anti-erbB antibodies, the patient is treated with anti-cancer radiation therapy. Administering the cytostatic agent (*i.e.*, the specific anti-erbB antibodies) followed by radiation results in an improved patient response.

Prior to the invention of the '558 patent, it was believed that anti-cancer radiation worked best on dividing cells. Therefore, conventional wisdom dictated that prior treatment with a cytostatic agent would not improve a patient's response to radiation therapy. Surprisingly, as described in the patent specification, erbB protein-mediated cancer cells first treated with a

cytostatic anti-erbB antibody and then exposed to anti-cancer radiation therapy demonstrated unexpectedly high levels of apoptosis, or programmed cell death.

The '558 patent is a continuation of U.S. Patent No. 6,417,168, and both patents claim priority to U.S. Provisional Application No. 60/076,788 which was filed on March 4, 1998. The application that resulted in the '558 patent was filed in March 2002 and was extensively examined by the U.S.P.T.O. before the '558 patent issued in December 2009. While Defendants make much ado about other applications in this patent family that were abandoned, there is nothing unusual or untoward about this type of patent prosecution strategy. Further, as the file history of this patent family makes clear, the U.S.P.T.O. carefully considered numerous prior art references, including references that form the centerpiece of Lilly's IPR petition.

Defendants point out that a European counterpart to the '558 patent, EP1058562, has been the subject of a European opposition proceeding. While the European patent was revoked, that case is currently on appeal. More importantly, standards for patentability in Europe and the United States are based on different criteria, and the revocation and subsequent appeal of a European counterpart does not impact validity of the patent-in-suit. As described above, despite participating in the European opposition proceeding and having first-hand knowledge of the art raised therein, Defendants did not challenge the '558 patent in the U.S until it became clear that they could not negotiate a license to the '558 patent on their preferred terms.

#### **B. Defendants' Infringing Conduct**

Defendants manufacture, market, sell, and distribute the anti-erbB antibody cetuximab under the trade name Erbitux. Erbitux has been approved by the U.S. Food and Drug Administration ("FDA") for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck (an erbB protein-mediated cancer also known as "locally or regionally advanced SCCHN") in combination with radiation therapy.

Defendants manufacture, market, sell, and distribute Erbitux with an FDA-approved label and package insert that instructs physicians to treat locally or regionally advanced SCCHN by administering Erbitux followed by administering anti-cancer radiation therapy. Defendants therefore actively encourage, instruct, and induce treating physicians to practice the claimed methods of the '558 patent.

### **C. The Litigation and Previous Licensing Negotiations**

To address the harm caused by Defendants' infringing conduct, Penn approached Lilly in the summer of 2015 to discuss a possible license to the '558 patent family. The parties entered into a Stand-Still Agreement in July 2015 which suspended all applicable statutes of limitations and further provided that neither party would be prejudiced by entering into licensing discussions. The parties commenced licensing negotiations, but were ultimately unsuccessful in reaching a business agreement.

Penn filed the instant case on November 13, 2015, immediately after expiration of the Stand-Still Agreement. (D.I. 1). Defense counsel subsequently contacted Penn's counsel to request a one-month extension to respond to Penn's complaint. After receiving assurances that Defendants needed the extension to prepare their response, Penn consented to the request, and the parties filed a Joint Stipulation to Extend Time for Defendants to Answer Complaint. (D.I. 11). The Court subsequently granted the stipulation. (D.I. 12).

### **D. Lilly's IPR Petition**

Lilly apparently made use of the 30-day extension to prepare its IPR petition, which Lilly filed on January 14, 2016, one day before filing its Answer to the Complaint and Counterclaims. The petition raises two alleged grounds of obviousness: (1) that a subset of claims is obvious in light of the Saleh, DeNardo, and Balaban references; and (2) that a smaller subset of claims is obvious in light of the Saleh, DeNardo, and Balaban references combined with U.S. Patent No.

4,945,102. The Saleh reference was submitted by the Penn inventors in an IDS and considered by the Examiner during prosecution of the '558 patent. Furthermore, the Saleh reference was cited and considered during prosecution of a related continuation application, and was withdrawn as a §102 reference after it was acknowledged that Saleh does not teach the claimed *order* of administration.<sup>2</sup> The Balaban reference was considered by the Examiner and overcome during the prosecution of the '558 patent, because it employs a *cytotoxic* antibody rather than a cytostatic antibody.<sup>3</sup> Therefore, neither Saleh nor Balaban would motivate one of ordinary skill in the art to ignore conventional wisdom and administer a cytostatic agent prior to radiation.

The '102 patent and DeNardo reference were not considered during prosecution. Lilly's IPR petition cites the '102 patent as a tertiary reference and relies on it as teaching the timing elements recited in claims 26-31. However, the '102 patent employs *cytotoxic* agents as radiosensitizers and is therefore cumulative to art considered and overcome during prosecution. The DeNardo reference is entirely irrelevant to the claims of the '558 patent, as it concerns radioimmunotherapy rather than radiation per se (commonly known as external beam radiation). Radioimmunotherapy works by an entirely different mechanism than radiation, and most importantly, does *not* work by killing dividing cells. Therefore, one of ordinary skill in the art would not be motivated by DeNardo to employ a cytostatic antibody in combination with radiation, which does work on dividing cells. In short, Lilly's IPR petition does not raise any new or meaningful attacks on the validity of the '558 patent and has a high likelihood of failing.

Lilly filed its IPR petition on January 14, 2016. Under the statutory framework of the Leahy-Smith America Invents Act, Penn has until April 15, 2016 to file a preliminary response. After the preliminary response has been filed, the PTAB has until July 15, 2016 to decide

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<sup>2</sup> Krumplitsch Decl., Ex. A, November 20, 2013 Non-Final Rejection.

<sup>3</sup> Krumplitsch Decl., Ex. B, Dec. 8, 2003 Information Disclosure Statement; Krumplitsch Decl., Ex. C, June 15, 2006 Non-Final Rejection.

whether to institute a trial of the challenged claims. If the PTAB grants Lilly's petition, its review will not be completed until 12-18 months after such grant, *i.e.*, as late as February 2018. At that time, either party may appeal the PTAB's decision to the Federal Circuit,<sup>4</sup> which would likely further delay final resolution of Lilly's IPR petition by an additional 6-12 months.

### III. LEGAL STANDARDS

"A patent is presumed to be valid, . . . and this presumption only can be overcome by clear and convincing evidence to the contrary." *Enzo Biochem, Inc. Gen-Probe Inc.*, 424 F.3d 1276, 1281 (Fed. Cir. 2005) (internal citation omitted). When an accused infringer requests to stay litigation pending review by the PTAB, as Defendants do here, this Court "is under no obligation to delay its own proceedings" to allow such review to proceed first, "regardless of [its] relevancy to infringement claims which the court must analyze." *Arkema Inc. v. Honeywell Int'l, Inc.*, Case No. 10-cv-2886, 2013 WL 5356844, at \*2 (E.D. Pa. Sept. 25, 2013) (quoting *NTP, Inc. v. Research in Motion, Ltd.*, 397 F. Supp. 2d 785, 787 (E.D. Va. 2005)). Instead, the decision of whether to grant a stay rests within the sound discretion of the court as a product of its inherent power to manage its own docket. *Cost Bros., Inc. v. Travelers Indemnity Co.*, 760 F.2d 58, 60 (3d Cir. 1985). This authority includes patent cases in which a review by the U.S.P.T.O. has been requested. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988).

In determining whether to stay an action pending *inter partes* review, courts consider the following factors: (1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set. *Destination Maternity Corp. v. Target Corp.*, 12 F. Supp. 3d 762, 766 (E.D. Pa. 2014) (quoting *Innovative Office Prods., Inc. v. Spaceco, Inc.*, Case No. 05-4037, 2008 WL 4083012, at \*2

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<sup>4</sup> 35 U.S.C. § 141(b).

(E.D. Pa. Aug. 28, 2008)). In analyzing the first factor, courts may consider four sub-factors: (a) the timing of the request for IPR; (b) the timing of the request for stay; (c) the status of the IPR proceedings; and (d) the relationship of the parties. *SenoRx, Inc. v. Hologic, Inc.*, Case No. 12-173-LPS-CJB, 2013 WL 144255, at \*6 (D. Del. Jan. 11, 2013). Significantly, it is well settled that “before a stay may be issued, the petitioner must demonstrate ‘a clear case of hardship or inequity,’ if there is ‘even a fair possibility’ that the stay would work damage on another party.” *Gold v. Johns–Manville Sales Corp.*, 723 F.2d 1068, 1075-76 (3d Cir. 1983) (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936)).

#### **IV. ARGUMENT**

##### **A. Entry Of A Stay Would Give Defendants A Tactical Advantage and Unduly Prejudice Penn**

Defendants appear to be using the IPR process to gain a tactical advantage in the litigation, which weighs heavily against a stay. Defendants ImClone and Lilly chose to attack the European counterpart to the '558 patent in the European Patent Office years ago. They did not mount such an attack in their primary market – the United States – until two months after Penn filed this litigation, and nearly seven months after Penn initiated licensing discussions with Lilly. As described above, once served with the Complaint, Defendants requested an extension, purportedly to prepare their Answer. It now appears that Lilly instead used that time to prepare its IPR petition. Other district courts have found that such behavior is grounds to deny a stay. In *Esco Corp. v. Berkeley Forge & Tool, Inc.*, the defendant “made no effort to seek reexamination of the patents-in-suit until it became apparent that . . . litigation was inevitable,” and commenced reexamination of the patent-in-suit “in anticipation of the Plaintiff’s filing suit following their unsuccessful negotiations.” No. C 09-1635 SBA, 2009 WL 3078463, at \*4 (N.D. Cal. Sept. 28, 2009). Concluding that “the record lends credence to Plaintiff’s assertion that Defendant is



attempting to use the reexamination process in order to gain a tactical advantage in the litigation,” the court denied a stay. *Id*

Further, Penn would be unduly prejudiced and disadvantaged by entry of a stay. Patent owners have the general right to timely enforce their patent rights. As courts have recognized, plaintiffs “will suffer some prejudice from a stay, due to loss of their chosen forum, the possibility of necessary witnesses’ memories fading, and negative impact on their ability to license the patent-in-suit.” *Benefit Funding Sys. LLC v. Advance Am., Cash Advance Centers, Inc.*, Case No. 12-801-LPS, 2013 WL 3296230, at \*2 (D. Del. June 28, 2013).

Defendants have not articulated any possible hardship or inequity if their motion for a stay is denied. Lilly chose to utilize the IPR process and cannot now complain that it is being prejudiced by having proceedings go forward in both fora. *See, e.g.*, Krumplitsch Decl., Ex. D, *Clouding IP, LLC v. SAP AG*, Case No. 13-1456-LPS, *Oral Order* (D.I. 35) (D. Del. Jan. 21, 2014) (noting that “the purported prejudice to [defendant] of having to litigate in the PTAB and this Court is entirely the result of [defendant’s] decision to file the petition for IPR”).

The remaining sub-factors, including timing, IPR status, and relationship between the parties, also weigh heavily against a stay.

### **1. Timing Factors and Status of the IPR Do Not Favor A Stay**

Defendants assert that because Lilly filed an IPR within two months of being sued for infringement,<sup>5</sup> and because Defendants filed for a stay the day after filing the petition,<sup>6</sup> those factors outweigh the significant fact that the motion to stay was filed long before the PTAB is even expected to act on the petition. At this stage, however, it is speculative whether the petition will be granted.

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<sup>5</sup> Defs.’ Mem. at 9.

<sup>6</sup> *Id.*

It will take approximately six months to receive the PTAB decision on whether to institute Lilly's IPR petition. During that time, the PTAB will take into consideration the challenged claims, Lilly's articulated grounds, and Penn's response. The PTAB will then determine if "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). The PTAB may choose to initiate a review on some or all of the challenged claims in the petition, and on some or all of the grounds set forth in the petition, or it may decline to initiate a review altogether. 37 C.F.R. § 42.108(a).

The threshold to submit an IPR petition to the PTAB is low. A party must submit the requisite fees, structure the petition in accordance with applicable regulations, and provide copies of required documents. "In view of this administrative framework, it seems clear that a stay of a patent infringement action is not warranted when based on nothing more than the fact that a petition for inter partes review was filed in the USPTO." *Automatic Mfg. Sys., Inc. v. Primera Tech., Inc.*, No. 6:12-cv-1727-Orl-37DAB, 2013 WL 1969247, at \*3 (M.D. Fla. May 13, 2013).

Other district courts deciding motions to stay filed before the PTAB reached an institution decision have either denied such motions as premature or postponed ruling on such motions until an institution decision has been reached. *See, e.g., Trover Grp., Inc. v. Dedicated Micros USA*, No. 2:13-CV-1047-WCB, 2015 WL 1069179, at \*4-6 (E.D. Tex. Mar. 11, 2015) (Bryson, J.); *TPK Touch Solutions, Inc. v. Wintek Electro-Optics Corp.*, No. 13-CV-02218-JST, 2013 WL 6021324, at \*4 (N.D. Cal. Nov. 13, 2013); *McRo, Inc. v. Bethesda Softworks LLC*, C.A. Nos. 12-1509, -1510, -1513, -1517, -1519-LPS-CJB, 2014 WL 1711028, at \*3 (D. Del. May 1, 2014); *Proctor & Gamble Co. v. Team Techs., Inc.*, No. 1:12-cv-552, 2013 WL 4830950, at \*3-4 (S.D. Ohio Sep. 10, 2013) (consolidating cases).

In 2014, the Federal Circuit issued an opinion on the closely related issue of whether a stay should be granted pending “covered business methods” review and held that it was not error for the district court to postpone ruling on the motion until the PTAB made a decision regarding institution. *VirtualAgility, Inc. v. Salesforce.com, Inc.*, 759 F.3d 1307, 1315-16 (Fed. Cir. 2014). Noting that some district courts have waited until post-grant review was instituted before ruling on a stay motion, while others denied as premature the motion to stay without prejudice to refile if post-grant review is instituted, the court expressed “no opinion” on which is the better practice. *Id.*

Lilly’s mere act of submitting a petition for IPR provides no basis for staying this case at the present time. At a minimum, the Court should deny the Defendants’ Motion to Stay with leave to renew once the PTAB acts on the petition and decides whether or not to even institute a review of any of the claims in the Patent-in-Suit. See *Derma Sciences, Inc. v. Manukamed Ltd.*, C.A. No. 12-3388-JAP, 2013 WL 6096459, at \*1 (D.N.J. July 18, 2013) (holding that defendant’s motion to stay should not be addressed until the PTAB has made a determination on the initial IPR petition). If the review is not instituted, the issue is moot. If, however, the PTAB does institute review, the Court will be able to better assess the effects, if any, of such review on this litigation. The Court will be in a better position at that time to make an informed decision about whether the IPR will actually simplify any issues before the Court.

## **2. Relationship of the parties**

Defendants also assert that a stay is appropriate here because the parties are not direct competitors.<sup>7</sup> The fact that Penn is not a pharmaceutical company and does not directly compete with Defendants does not automatically weigh in favor of granting a stay here. As the court in *Walker Digital, LLC v. Google, Inc.*, noted:

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<sup>7</sup> Defs.’ Mem. at 10

Although it is true that Plaintiff Walker Digital does not actively practice the patents and, therefore, does not compete with Google, it is also true that the longer Google is allowed to engage in allegedly infringing activity, the lower the value of the patents becomes as licensing assets.

C.A. No. 11- 318-LPS, 2014 WL 2880474, at \*1 (D. Del. June 24, 2014). The situation here is similar—the longer Defendants are allowed to engage in allegedly infringing activity, the lower the value of the patents becomes as licensing assets. As described above, Defendants appear to be opposed to a timely resolution of this dispute, to Penn’s detriment.

#### **B. The Potential for Simplification of the Issues is Speculative at Best**

Defendants’ argument about the potential for simplification of the issues is grossly overstated. Defendants do not have a strong prior art position, as the petition does not present new or significant invalidity arguments. As already noted, the art relied on in the petition either was previously before the PTO, is cumulative to art that the PTO considered, or is entirely irrelevant to the claimed invention. Moreover, Defendants’ arguments about the validity of claims in Penn’s other U.S. and foreign patent applications are red herrings. Indeed, notwithstanding Lilly’s and ImClone’s active participation in the longstanding opposition proceedings against the European counterpart to the ’558 patent, Defendants chose to launch an attack on the ’558 patent in the U.S.P.T.O. only after licensing discussions fell through and litigation ensued. If Defendants had felt confident about their chances of invalidating the ’558 patent, presumably they would have filed an IPR petition or reexamination request long ago in order to immunize their Erbitux manufacturing and sales activities in their largest market, just as they initiated opposition proceedings in Europe. Thus, a finding by the PTAB that all 32 claims at issue in the petition are unpatentable is among the least likely of many possible outcomes. Any potential for simplification of the issues in the litigation cannot be judged based solely on

the IPR outcome most favorable to Defendants. *See Automatic Mfg. Sys., Inc.*, 2013 WL 1969247, at \*2-3.

Other district courts have found that to “truly simplify the issues ... the outcome of the reexamination must finally resolve all issues in the litigation.” *See Largan Precision Co. v. Fujifilm Corp.*, No. C 10-1318 SBA, 2011 WL 794983, at \*3 (N.D. Cal. Mar. 1, 2011) (“If regardless of the result of the reexamination, there are still claims or counterclaims that need to be resolved by the Court, then reexamination clearly fails to provide final resolution.”); *see also Alps South, LLC v. The Ohio Willow Wood Co.*, No. 8:09-cv-386-T-EAK-MAP, 2010 WL 2465176, at \*2 (M.D. Fla. Jun. 16, 2010) (denying stay where it was “likely that some or all of the claims will have to be litigated notwithstanding reexamination”). The same considerations apply to *inter partes* review.

To that end, in the likely event that Defendants fail to invalidate at least some of the challenged claims before the PTAB, they will likely attack those same claims in the litigation (in addition to their attacks on claims 32-40, as those claims are not challenged in Lilly’s petition). For example, Defendants would likely continue to pursue their §101, 112, and 116 invalidity challenges, and also would likely pursue §102 and 103 invalidity challenges to which no estoppel applies as result of the IPR proceeding at the PTAB.<sup>8</sup> Such invalidity challenges, as well as the parties’ other claims and defenses, would remain in the litigation.

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<sup>8</sup> IPR includes an estoppel provision that prevents a petitioner from later raising in a district court any ground of invalidity that the petitioner raised or reasonably could have raised in the IPR petition. Estoppel from an IPR attaches after the PTAB has granted the petition and issued a final written decision. Because an IPR petition is restricted to grounds that could be raised under §§102 or 103 and only on the basis of prior art consisting of patents or printed publications, any potential estoppel is similarly restricted. Thus, if Lilly’s petition is granted but ultimately fails to invalidate all challenged claims, Lilly would still be permitted to litigate its §§ 101, 112, and 116 validity attacks, as well as §§102 and 103 challenges based on prior art references that Lilly did not raise and could not reasonably have raised in the IPR.

### **C. Stage of discovery**

Contrary to Defendants' assertions, discovery in this case is progressing. On January 22, 2016, Penn served an initial set of interrogatories and requests for documents on Defendants. The parties held their initial Rule 26(f) conference on January 26, 2016 and filed a Joint Report on the Rule 26(f) conference on January 27, 2016, which includes competing proposed case schedules. The parties have exchanged Fed. R. Civ. P. 26(a) initial disclosures, ESI disclosures pursuant to paragraphs 2–4 of the Court's Draft Order Governing Electronic Discovery, and drafts of a proposed electronic discovery order. Notably, Penn has requested a case schedule consistent with both the just and speedy resolution goals of Fed. R. Civ. P.1 and this Court's past case management practices. Further, the Court has set the initial Rule 16(b) conference for tomorrow, February 2, 2016. In short, discovery has begun, and this case is progressing as it should.

### **V. CONCLUSION**

For the reasons set forth above, Penn respectfully submits that a stay is not warranted in this case and requests that the Court deny Defendants' Motion to Stay Pending *Inter Partes* Review in full, or alternatively, deny said Motion as premature.

Dated: February 1, 2016

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

The undersigned certifies that the foregoing document was served on counsel for Defendants Eli Lilly and Company, ImClone LLC and Bristol Myers Squibb Company by email.

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